



INDUS JOURNAL OF BIOSCIENCES RESEARCH

<https://induspublisher.com/IJBR>

ISSN: 2960-2793/ 2960-2807



Myringotomy vs. Myringotomy with Grommet Insertion for Treatment of Secretory Otitis Media with Effusion

Muhammad Tariq¹, Habiburehman Afridi¹, Ahmed Haris Khan¹¹Department of ENT, MTI-Lady Reading Hospital, Peshawar, KP, Pakistan.

ARTICLE INFO

Keywords

Otitis Media with Effusion, Myringotomy, Grommet Insertion, Hearing Improvement, Tympanogram Improvement.

Corresponding Author: Habiburehman Afridi,

Department of ENT, MTI-Lady Reading Hospital, Peshawar, KP, Pakistan.

Email: drhabibafridi1@gmail.com

Declaration

Author's Contributions: All authors contributed to the study and approved the final manuscript.

Conflict of Interest: The authors declare no conflict of interest.

Funding: No funding received.

Article History

Received: 10-10-2024

Revised: 29-11-2024

Accepted: 07-12-2024

ABSTRACT

Background: This study compares the effectiveness of myringotomy alone versus myringotomy with grommet insertion in managing secretory otitis media with effusion (OME). The findings will assist clinicians in selecting the optimal treatment approach, ensuring timely and effective hearing restoration to support better language development in affected patients. To evaluate and compare the outcomes of myringotomy versus myringotomy with grommet insertion for the treatment of OME. **Methods:** The study design was a Randomized controlled trial conducted at the Department of ENT, Lady Reading Hospital, Peshawar, from June 10, 2023, to December 10, 2023. Male and female patients aged 1 to 15 diagnosed with OME were included in the study. Participants were randomised into two equal groups: Group A (myringotomy with grommet insertion) and Group B (myringotomy alone). Treatment response was assessed based on hearing improvement, and tympanogram results two weeks after the intervention. **Results:** The mean age of patients was 9.67 ± 2.84 years in Group A and 10.27 ± 2.59 years in Group B. The male-to-female ratio was 2.3:1 in Group A and 1.6:1 in Group B. Hearing improvement was observed in 91.6% (76/83) of patients in Group A, compared to 81.9% (68/83) in Group B. Tympanogram improvement was noted in 94.0% (78/83) of patients in Group A and 84.3% (70/83) in Group B. **Conclusion:** Myringotomy with grommet insertion showed superior hearing and tympanogram improvement outcomes compared to myringotomy alone. This highlights the importance of grommet insertion as an effective intervention for OME.

INTRODUCTION

Otitis media with effusion (OME), commonly known as "glue ear," occurs when fluid accumulates in the middle ear without signs of acute infection[1]. This condition is a leading cause of hearing difficulties in children and can significantly impact their speech and language development. The primary causes include Eustachian tube dysfunction, impaired drainage and ventilation in the middle ear, and upper respiratory tract infections. Left untreated, OME can lead to complications such as persistent hearing loss and delays in cognitive and social development[2].

OME is particularly common in children under five, with many experiencing at least one episode during their early years[3]. Specific populations, such as children with anatomical conditions like cleft palate or Down syndrome, are at higher risk due to their predisposition to Eustachian tube dysfunction [4, 5]. In many cases, OME may go unnoticed until symptoms, such as subtle hearing loss or speech delays, become apparent. Therefore, early detection and treatment are critical in preventing long-term effects on a child's development[6].

One of the primary treatment methods for OME is myringotomy, a surgical procedure where



a small incision is made in the eardrum to drain fluid and relieve pressure. Over time, an additional step involving the placement of a ventilation tube, or grommet, has gained popularity[7]. This procedure helps maintain prolonged aeration of the middle ear, reducing the likelihood of fluid reaccumulation and recurrence [8]. However, its routine use raises questions regarding the balance of benefits and risks.

The debate surrounding myringotomy with and without grommet insertion centres on their comparative effectiveness in improving hearing and tympanogram results. Advocates of grommet insertion highlight its ability to offer sustained benefits, particularly in recurrent or chronic OME cases [9]. However, potential drawbacks, including the risk of infection or complications such as persistent eardrum perforation, necessitate a closer evaluation of both procedures to determine their respective advantages.

This study compares myringotomy vs myringotomy with grommet insertion to treat secretory otitis media with effusion. It focuses on key measures such as hearing improvement and tympanogram changes over a defined follow-up period. By employing a randomised controlled design, this research ensures that the results provide a reliable basis for clinical decision-making, contributing to evidence-based practices in otolaryngology.

Ultimately, this research seeks to guide healthcare professionals in identifying the most effective treatment for OME, a condition with significant implications for a child's auditory and developmental health. By addressing these critical questions, the findings aim to enhance clinical care, support timely intervention, and improve outcomes for children, helping them achieve better hearing and overall quality of life.

METHODOLOGY

This study was a randomised controlled trial conducted in the Department of ENT - Head and Neck Surgery at Lady Reading Hospital, Peshawar, over six months, from June 10, 2023, to December 10, 2023. Ethical approval was obtained from the hospital's Ethical Committee (Ref. No.CPSP/REU/ENT-2020-022-1182).

The sample size for this study was determined using the WHO sample size calculator, ensuring

robust statistical power. The parameters used included a significance level of 5% and a statistical power of 80%, ensuring reliable detection of differences between the groups. The anticipated population proportions were set at 48% and 67%, reflecting expected outcomes based on prior research. This calculation yielded a total sample size of 166 patients, equally divided into two groups of 83 participants. These parameters were chosen to provide sufficient power to detect clinically meaningful differences in outcomes between the intervention and control groups.

The study included 166 patients aged 2–15 years diagnosed with otitis media with effusion (OME). Patients were randomly assigned to either Group A (myringotomy with grommet insertion, n=83) or Group B (myringotomy alone, n=83). Randomisation was performed using block randomisation to ensure equal group sizes. Patients were recruited through non-probability consecutive sampling.

Inclusion and Exclusion Criteria

The study included patients diagnosed with secretory otitis media (OME) who met the following criteria: a history of hearing loss and recurrent upper respiratory tract infections, findings of a dull and immobile tympanic membrane on otoscopy, and hearing impairment confirmed through voice and tuning fork tests. Tympanometry results indicating a Type B tympanogram and a lack of response to medical treatment for at least three months were also required. Eligible participants were aged 2–15, of either gender and deemed fit for surgery based on a favourable pre-anaesthetic evaluation report. Patients were excluded if they had recurrent otitis media, active ear discharge, or a bleeding disorder that would contraindicate surgical intervention.

All patients underwent baseline evaluations, including otoscopy, tuning fork tests, and tympanometry. Medical management consisting of antibiotics, antihistamines, nasal decongestants, and steroids was provided before surgical intervention.

- **Group A:** Patients received myringotomy followed by grommet insertion under general anaesthesia. The grommet was placed to facilitate long-term aeration of the middle ear.

- **Group B:** Patients underwent myringotomy alone, with the tympanic membrane left to heal without grommet placement.

Both procedures were conducted using standard aseptic techniques. Postoperative management included antibiotics, nasal decongestants, and ear water precautions. Patients were assessed at two weeks, one month, and three months post-surgery. Outcomes were evaluated based on tympanometry and hearing improvement using voice tests and tuning fork assessments.

The primary outcomes were:

1. Hearing improvement, assessed through clinical hearing tests.
2. Tympanogram improvement, evaluated using tympanometry.

Data were analysed using SPSS version 22. Descriptive statistics were used to summarise demographic variables, with mean \pm standard deviation for continuous data and frequencies/percentages for categorical data. Comparisons of hearing and tympanogram improvements between groups were performed using the chi-square test. Stratification by age and gender was conducted to control confounding variables. A p-value <0.05 was considered statistically significant.

RESULTS

The study compared outcomes between Myringotomy and Myringotomy with Grommet insertion in managing secretory otitis media with effusion. Baseline characteristics showed that the mean age was slightly lower in the Myringotomy with the Grommet group (9.67 ± 2.84 years) compared to the Myringotomy group (10.27 ± 2.59 years). Similarly, BMI was comparable, with values of 23.9 ± 2.49 and 24.6 ± 2.78 , respectively, indicating a balanced demographic distribution between the groups.

Table 1

Mean \pm Standard Deviation According to Age and BMI N = 166 (Myringotomy with Grommet group = 83, Myringotomy group = 83)

Baseline characteristics	Mean \pm standard deviation	
	Myringotomy with Grommet Group	Myringotomy Group
Age (yrs)	9.67 ± 2.84	10.27 ± 2.59
BMI (Kg/m ²)	23.9 ± 2.49	24.6 ± 2.78

Age and gender distribution revealed that the majority of patients in both groups were children aged ≤ 10 years, with a slightly higher percentage in the Myringotomy with Grommet group (72.3%) compared to the Myringotomy group (67.5%). For patients older than 10 years, the Myringotomy group had a marginally more significant proportion (32.5%) than the Grommet group (27.7%). Gender analysis demonstrated that males were predominant in both groups, constituting 69.9% in the Myringotomy with Grommet group and 61.4% in the Myringotomy group, while females made up 30.1% and 38.6%, respectively.

Table 2

Frequency of Age and Gender Distribution Between Groups

Age/Gender	Myringotomy with Grommet (Freq, %)	Myringotomy (Freq, %)
≤ 10 years	60 (72.3%)	56 (67.5%)
> 10 years	23 (27.7%)	27 (32.5%)
Male	58 (69.9%)	51 (61.4%)
Female	25 (30.1%)	32 (38.6%)

The frequency of hearing Myringotomy with grommet group exhibited better outcomes, with 91.6% of patients improving compared to 81.9% in the Myringotomy group. However, while clinically significant, the difference did not achieve statistical significance ($p=0.067$). The hearing tympanogram improvement was more pronounced in the Myringotomy with the Grommet group (94.0%) than in the Myringotomy group (84.3%), and this was statistically significant ($p=0.045$).

Table 3

Frequency of Hearing and Tympanogram Improvement Across Groups

Improvement Type	Myringotomy with Grommet (Freq, %)	Myringotomy (Freq, %)	P Value
Hearing Improvement - Yes	76 (91.6%)	68 (81.9%)	0.067
Hearing Improvement - No	7 (8.4%)	15 (18.1%)	
Tympanogram Improvement - Yes	78 (94.0%)	70 (84.3%)	0.045
Tympanogram Improvement - No	5 (6.0%)	13 (15.7%)	

When hearing improvement was stratified by age, children aged ≤ 10 years in the Grommet group had better improvement rates (91.7%) compared to

those in the Myringotomy group (82.1%). However, the difference was not statistically significant ($p=0.126$). Similarly, in patients aged >10 years, the Grommet group showed better hearing improvement (91.3%) compared to the Myringotomy group (81.5%), but the p -value (0.318) indicated no statistical significance. Gender stratification revealed that males in the Grommet group achieved 89.6% improvement compared to 82.3% in the Myringotomy group, with no significant difference ($p=0.269$). Among females, the Grommet group demonstrated a higher improvement rate (96.0%) compared to the Myringotomy group (81.2%), approaching statistical significance ($p=0.092$).

Table 4

Hearing Improvement Stratified by Age and Gender

Age/Gender	Group	Hearing Improvement Yes (%)	Hearing Improvement No (%)	P value
≤ 10 years	Myringotomy with Grommet	91.7%	8.3%	0.126
	Myringotomy	82.1%	17.9%	
>10 years	Myringotomy with Grommet	91.3%	8.7%	0.318
	Myringotomy	81.5%	18.5%	
Male	Myringotomy with Grommet	89.6%	10.4%	0.269
	Myringotomy	82.3%	17.7%	
Female	Myringotomy with Grommet	96.0%	4.0%	0.092
	Myringotomy	81.2%	18.8%	

Stratification of tympanogram improvement showed similar trends. In children aged ≤ 10 years, the Grommet group showed 93.3% improvement versus 85.7% in the Myringotomy group ($p=0.531$). Among patients older than 10 years, the Grommet group had a 95.6% improvement rate compared to 81.5% in the Myringotomy group ($p=0.178$). Gender-based analysis revealed significant differences in males, where the Grommet group had a higher improvement rate (94.8%) than the Myringotomy group (81.5%), with a statistically significant p -value of 0.037. Among females, improvement was 96.0% in the Grommet group compared to 81.2% in the Myringotomy group, though the difference was not statistically significant ($p=0.092$).

Table 5

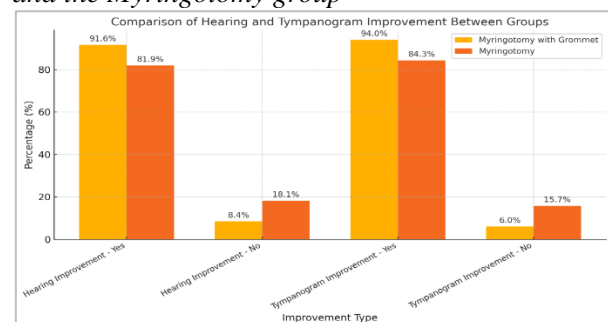
Tympanogram Improvement Stratified by Age and Gender

Age/Gender	Group	Tympanogram Improvement Yes (%)	Tympanogram Improvement No (%)	P Value
≤ 10 years	Myringotomy with Grommet	93.3%	6.7%	0.531
	Myringotomy	85.7%	14.3%	
>10 years	Myringotomy with Grommet	95.6%	4.4%	0.178
	Myringotomy	81.5%	18.5%	
Male	Myringotomy with Grommet	94.8%	5.2%	0.037
	Myringotomy	81.5%	18.5%	
Female	Myringotomy with Grommet	96.0%	4.0%	0.092
	Myringotomy	81.2%	18.8%	

In conclusion, the Myringotomy with Grommet insertion consistently demonstrated better outcomes in terms of hearing and tympanogram improvements compared to Myringotomy alone. While some differences were not statistically significant, the clinical relevance of these findings supports the effectiveness of Grommet insertion, particularly for achieving improved tympanogram outcomes and hearing restoration in patients with secretory otitis media.

Figure 1

Compares hearing and tympanogram improvement between the Myringotomy with Grommet group and the Myringotomy group



It reveals that the Grommet group consistently achieved better outcomes. Hearing improvement was observed in 91.6% of the Grommet group compared to 81.9% in the Myringotomy group, while tympanogram improvement occurred in 94.0% of the Grommet group versus 84.3% in the Myringotomy group. Conversely, fewer patients in

the Grommet group experienced no improvement, with only 8.4% and 6.0% reporting no hearing and tympanogram improvement, respectively, compared to 18.1% and 15.7% in the Myringotomy group. These results highlight the clinical advantage of Grommet insertion in improving hearing and tympanogram outcomes for patients with secretory otitis media.

DISCUSSION

Otitis media with effusion (OME), also known as "glue ear," is a condition characterised by fluid accumulation in the middle ear without signs of infection. It often manifests as hearing impairment, ear fullness, or inattentiveness, especially in children. In this study, a higher prevalence of OME was observed among males, consistent with findings from prior research[10, 11] that suggest societal and possibly biological factors contribute to this gender disparity.

The majority of patients in this study presented with hearing loss as the primary complaint (68%), followed by ear blockage (14%), nasal obstruction (12%), and sore throat (6%). These results align with findings from other studies where hearing loss is the most common symptom of OME, often preceding other complaints [1, 12, 13]. This underscores the importance of early detection and intervention, particularly in populations with limited routine screening, as delays in addressing hearing impairment can profoundly impact language development and academic performance.

On otoscopic examination, retracted tympanic membranes were the most frequent finding (66%), followed by bulging membranes (24%), dull membranes (8%), and normal membranes (2%). These findings were comparable to previous studies, which reported a predominance of retracted membranes in OME cases [14, 15]. The degree of conductive hearing loss observed in this study ranged from 20 to 45 dB, with a mean of 29.20 dB. This was consistent with international data[16]. However, a slightly higher degree of hearing loss was observed in this population, potentially due to delayed diagnosis, limited access to medical care, and environmental factors such as poor hygiene and recurrent infections.

The comparative outcomes of myringotomy with and without grommet insertion were assessed through both subjective evaluation and objective

measurements using tympanometry and audiometry. On the seventh postoperative day, 98% of patients treated with grommet insertion showed improved hearing compared to 82% in the myringotomy-only group. By the 30th postoperative day, 88% of patients in the grommet group exhibited hearing improvement compared to 34% in the myringotomy-only group, with the difference being statistically significant ($p=0.014$). These results highlight the effectiveness of grommet insertion in maintaining middle-ear aeration and addressing the underlying Eustachian tube dysfunction that often persists after myringotomy alone [17].

Tympanogram results also demonstrated the grommet group's superior performance, with significant improvements observed at follow-up visits. Tympanogram improvement was particularly pronounced in males, where the grommet group achieved a statistically significant advantage ($p=0.037$) over the myringotomy-only group. The grommet group showed a higher improvement rate among females, although the difference was not statistically significant.

The findings align with existing literature[18, 19], consistently supporting ventilation tube insertion as the preferred surgical treatment for persistent OME. Grommets reduce the likelihood of fluid reaccumulation and the associated risk of recurrent OME by providing prolonged aeration of the middle ear. Studies have shown that grommets can significantly decrease the duration of effusion and improve hearing outcomes compared to myringotomy alone[19, 20]. However, it is essential to note that grommet insertion is not without limitations. Studies report a 20% to 50% recurrence rate following tube extrusion, which may require additional surgical interventions, such as adenoidectomy, to address persistent Eustachian tube dysfunction[21, 22].

In conclusion, this study demonstrates that myringotomy with grommet insertion offers superior outcomes compared to myringotomy alone for treating OME. The findings underscore the importance of incorporating grommet insertion into treatment plans, particularly for cases unresponsive to medical therapy. Future research should explore long-term outcomes, recurrence rates, and strategies to optimise the management of OME further.

CONCLUSION

This study demonstrates that myringotomy with ventilation tube insertion yields superior outcomes compared to myringotomy alone in treating otitis media with effusion. Patients treated with ventilation tube insertion showed significantly better hearing improvement and tympanogram results, emphasising the procedure's effectiveness in managing this condition.

The findings support the recommendation of myringotomy with ventilation tube insertion as a first-line surgical treatment, particularly for children with persistent OME who do not respond

to medical therapy. Additionally, combining this approach with adenoidectomy may further enhance outcomes and reduce the likelihood of recurrence in selected cases.

By addressing the underlying issues of Eustachian tube dysfunction and fluid accumulation, this intervention provides a reliable solution to prevent the long-term complications of OME, such as hearing loss and delayed language development. Future studies should evaluate long-term outcomes and explore strategies to minimise effusion recurrence post-treatment.

REFERENCES

1. Oner, F. (2024). Otitis media with effusion. *Infections in Otolaryngology*, 177-190. <https://doi.org/10.69860/nobel.9786053359401.12>
2. Kar, M., Bayar Muluk, N., & Negm, H. (2023). Otitis media with effusion and hearing loss in children. *Comprehensive ENT*, 227-238. https://doi.org/10.1007/978-3-031-38495-0_17
3. AHM, D. (2020). Adenoids with glue ear: Incidence, management and outcome. *Global Journal of Medical Research*, 1-8. <https://doi.org/10.34257/gjmrjvol20is4pg1>
4. Sait, S., Alamoudi, S., & Zawawi, F. (2022). Management outcomes of otitis media with effusion in children with Down syndrome: A systematic review. *International Journal of Pediatric Otorhinolaryngology*, 156, 111092. <https://doi.org/10.1016/j.ijporl.2022.111092>
5. Wong, S. J., & Carvalho, D. (2023). Otitis media in special populations. *Textbook of Otitis Media*, 245-252. https://doi.org/10.1007/978-3-031-40949-3_28
6. Bernkopf, E., Cristalli, G., De Vincentiis, G. C., Bernkopf, G., & Capriotti, V. (2022). Temporomandibular joint and otitis media: A narrative review of implications in Etiopathogenesis and treatment. *Medicina*, 58(12), 1806. <https://doi.org/10.3390/medicina58121806>
7. Rasheed, A. M., Abbas, A. M., Hilal, S. A., & Homadi, N. J. (2023). Adenoidectomy and endoscopic myringotomy with and without ventilation tube insertion for treatment of otitis media with effusion in 6-12 years old children. *The International Tinnitus Journal*, 27(1). <https://doi.org/10.5935/0946-5448.20230005>
8. Alaraifi, A. K., Alkhaldi, A. S., Ababtain, I. S., & Alsaab, F. (2021). Predictors of otitis media with effusion recurrence following myringotomy. *Indian Journal of Otolaryngology and Head & Neck Surgery*, 74(S3), 4053-4058. <https://doi.org/10.1007/s12070-021-02817-0>
9. Das, A., Mitra, S., & Hazra, S. (2022). *Surgical Atlas of Transcanal Endoscopic Ear Surgery: A Step by Step Guide*. Jaypee Brothers Medical Publishers.
10. Saad, K., Abdelmoghny, A., Abdel-Raheem, Y. F., Gad, E. F., & Elhoufey, A. (2021). Prevalence and associated risk factors of recurrent otitis media with effusion in children in Upper Egypt. *World Journal of Otorhinolaryngology - Head and Neck Surgery*, 7(4), 280-284. <https://doi.org/10.1016/j.wjorl.2020>

- 08.002
11. Riaz, N., Ajmal, M., & Khan, M. S. (2022). Frequency of otitis media with effusion among children aged 1-5 years presenting to immunization center of tertiary care hospitals, Rawalpindi. *World Journal of Otorhinolaryngology-Head and Neck Surgery*, 8(04), 315-320.
 12. Elhakeem, A. A., Al Shawabkeh, M. A., & Haidar, H. (2020). Otitis media with effusion (OME). *Textbook of Clinical Otolaryngology*, 57-62. https://doi.org/10.1007/978-3-030-54088-3_4
 13. Swain, S. K., & Dubey, D. (2024). Current practice for management of otitis media with effusion in children – A review. *Medical Journal of Dr. D.Y. Patil Vidyapeeth*, 17(Suppl 2), S263-S268. https://doi.org/10.4103/mjdrdypu.mjdrdypu_658_23
 14. Jamal, A., Alsabea, A., Tarakme, M., & Safar, A. (2022). Etiology, diagnosis, complications, and management of acute otitis media in children. *Cureus*. <https://doi.org/10.7759/cureus.28019>
 15. Onwughalu, B., Adekanye, A., Mgbe, R., Anisi, C., Umana, A., & Somefun, O. (2024). Assessment of prevalence of otitis media with effusion and correlation between Otolaryngoscopic findings with Jerger's diagnostic Tympanograms among pupils in Calabar municipality. *Nigerian Journal of Clinical Practice*, 27(9), 1112-1119. https://doi.org/10.4103/njcp.njcp_332_24
 16. Ravi, D., NK, B., & SR, J. (2024). A prospective observational study on Tympanometric screening for otitis media with effusion in children with upper respiratory tract infections in a tertiary care centre. *SSR Institute of International Journal of Life Sciences*, 10(5). <https://doi.org/10.21276/sr-ijls.2024.10.5.17>
 17. Abdelazim, M., Zaghloul, A., & Elbakly, M. (2020). Prevalence of otitis media with effusion in children of Damietta Governorate (Egypt). *International Journal of Medical Arts*, 0(0), 0-0. <https://doi.org/10.21608/ijma.2020.23147.1092>
 18. MacKeith, S., Mulvaney, C. A., Galbraith, K., Webster, K. E., Connolly, R., Paing, A., Marom, T., Daniel, M., Venekamp, R. P., Rovers, M. M., & Schilder, A. G. (2023). Ventilation tubes (grommets) for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews*, 2023(11). <https://doi.org/10.1002/14651858.cd015215.pub2>
 19. Abdel Tawab, H. (2020). Myringotomy with versus without grommet tube insertion in chronic serous otitis media with effusion : Southern Oman experience. *Egyptian Journal of Ear, Nose, Throat and Allied Sciences*, 21(2), 82-87. <https://doi.org/10.21608/ejentas.2020.19010.1155>
 20. Akhtar, S., Gul, U., Jawaid, A., Azam, K., Niazi, M. S., & Najam, A. (2021). Myringotomy for the treatment of otitis media with effusion; A comparison in the outcome with and without grommet insertion. *PAFMJ*, 71(Suppl-3), S521-25. <https://doi.org/10.51253/pafmj.v71isuppl-3.7920>
 21. Hidaka, H., Ito, M., Ikeda, R., Kamide, Y., Kuroki, H., Nakano, A., Yoshida, H., Takahashi, H., Iino, Y., Harabuchi, Y., & Kobayashi, H. (2023). Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan – 2022 update. *Auris Nasus Larynx*, 50(5), 655-699. <https://doi.org/10.1016/j.anl.2022.12.004>
 22. Toivonen, J. SURGICAL TREATMENT OF OBSTRUCTIVE EUSTACHIAN TUBE DYSFUNCTION. <https://www.utupub.fi/bitstream/handle/10024/177039/AnnalesD1789Toivonen.pdf?sequence=1>